## REMARKS

Claims 1-14 are canceled and new claims 19-27 are added herein. The claims have been amended to point out the invention more distinctly. Support for the new claims is found throughout the specification but in particular on page 4, lines 13-26 and on page 5, lines 3-10, in the Examples, as well as in the claims as originally filed. The phospholipid concentration indicated in claim 21 is evident in Examples 1-5. No new matter has been added and entry of the amendment is respectfully requested.

**The rejections under 35 U.S.C. § 112, second paragraph**

Based upon the foregoing claim cancellations, the bases for these rejections are rendered moot, withdrawal is respectfully requested.

**The Rejections under 25 U.S.C. § 102(e)**

The Examiner has rejected claims 1-14 under 35 U.S.C. § 102(e) as allegedly anticipated by Mehansho et al. (U.S. Patent No. 5,707,670). In this rejection the Examiner has asserted that based on Mehansho the overall concept of encapsulating vitamins and nutrients within bilayered liposomes was known, as was their drying and use in infant formulas. Moreover, the Examiner has asserted that other components of the presently claimed liposomal formulations are inherently disclosed as well, absent evidence and arguments to the contrary. The rejection is inapplicable to the new claims.

Mehansho is directed to producing chocolate milk formulations, which formulations purportedly mask the taste of particular ingredients such as iron. The present claims are limited to liposomal-based infant formula preparations. This distinction is important to note because of the discovery that liposomes are present in human milk (*see* specification at page 4, lines 13-14). The preparation of the presently claimed liposomal-based infant formulas allows said formulas to more closely resemble natural human milk (*see* specification at page 4, lines 24-25). Further, the inclusion of a phospholipid component in the claimed formulas at the same concentration as that

found in human milk has the added benefit of enhancing the bioavailability of encapsulated nutrients. Previous infant formulas have not included liposomes and have failed to produce a close substitute to human milk. Respectfully, Mehansho does not disclose preparations which would closely resemble the composition of human milk and would be useful as an infant formula. In addition, Mehansho does not teach, neither expressly nor inherently, the phospholipid concentration of the present claims and its preparations. And, unlike the present claims, which are directed to liposome preparations, it is unclear whether Mehansho discloses a liposome preparation.

**Phospholipid Concentration and Size**

The concentration of "emulsifier" exemplified by Mehansho is between 0.03 to 0.04% of the total composition when the emulsifier is in a final liquid product (*see* Mehansho's Examples). It is unclear how much of this "emulsifier" percentage is comprised of a phospholipid component, however, for purposes of responding to the Examiner's assertion it may be assumed to comprise the total percentage presented above. In contrast, the currently pending claims include the limitation that the liposome formulations have a phospholipid concentration of at least about 0.1% w/w of the infant formula liposome preparation (*See e.g.*, Examples 1-5; and specification at page 5, line 7). This percentage clearly lies outside of the phospholipid concentration disclosed in Mehansho. Thus, Mehansho does not teach compositions which expressly (nor inherently, see below) contain this percentage of phospholipids.

In addition, current Claim 27 is directed to liposomal preparations useful as infant formula within the size range of about 50nm to about 100nm. Respectfully, there is no indication that if Mehansho's preparations are liposome preparations, that the size of said liposomes are within the currently claimed range. In fact, liposome size may vary within a large range based on the method of preparation, from 10nm to over 500nm. *See* S. S. Chrai et al., BioPharm 10-14 (November 2001).

invention contemplates a phospholipid concentration which is the same as that found in human milk. And, as provided in the present specification, liposomes are present in human milk due to this phospholipid concentration (*see also* Keller et al., Agro-food-Industry Hi-Tech 11: 6 (May/June 2000)).

**Inherency**

As mentioned above, Mehansho does not inherently disclose the subject matter of the present claims. Inherency requires that "the missing descriptive matter is necessarily present in the thing described in the reference and it would be so recognized by persons of ordinary skill." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Therefore, the disclosed subject matter in the present claims must naturally flow from the Mehansho disclosure.

Respectfully, the currently claimed phospholipid concentration does not naturally flow from Mehansho's disclosure. As provided above, only recently were phospholipid containing liposomes discovered to exist in human milk. The current claims include a phospholipid concentration which is engineered to mimic that found in human milk and is at least two and a half times higher (w/w) than the concentration taught by Mehansho. Therefore, this phospholipid concentration is not necessarily present in Mehansho and, even if it were, it would not be recognized by one of skill in the art due to the discovery described above and the variation in the objects of the present invention (infant formula) versus Mehansho (chocolate milk formulations).

In addition, the currently claimed liposome size is not necessarily present in Mehansho's preparations because, as provided in *Continental Can*, inherency cannot be established by possibilities and probabilities. *Id* at 1749. It would merely be a possibility that Mehansho's preparations include liposomes of the size claimed.

Based on the foregoing, the Applicants respectfully assert that Mehansho is inapplicable to the new claims because it does not disclose every element of the claims neither expressly nor inherently.

For the foregoing reasons, it is believed that claims 19-27 are clearly patentable over the prior art cited.

## CONCLUSION

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. 270142000300.

Respectfully submitted,

Dated: March 26, 2002 By: _____

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